REMARKS

The specification has been amended in paragraph 8 to correct a spelling error by replacing "palmiate" with "palmitate."

Paragraph 8 of the specification has also been amended to add, "The fat-soluble active ingredient may be a plant or animal oil or fat, particularly sunflower oil, palm oil or corn oil." Support is found in original claim 7. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973); and MPEP §§ 608.01(o) and (l).

Claims 1, 11, 12, 13, and 18 have been amended to recite "native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt.-%." Support for the amendments is found in the specification at, for example, Paragraph 4, lines 1-4 and 7-10[1]; and in original claims 1 and 2. (Id.)

Claims 2-4 and 19 have been canceled without prejudice.

Claims 6 and 10 were previously canceled without prejudice.

Claim 7 has been amended to recite "[t]he formulation according to claim 1, comprising additionally a plant or animal oil or fat." Claim 21 has been amended to recite "[t]he formulation according to claim 20, comprising additionally a plant or animal oil or fat." Support for the amendments is found, for example, in paragraph 8, paragraph 15, and paragraph 17; and claims 1, 6, and 7 as originally filed. (Id.) See in particular original claim 7. (Id.)

No new matter has been added.

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[1] Where the specification is referenced, the published application, U.S. 2006/0257453, is cited.

Written Description Rejection

Claims 7 and 21 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. (Paper No. 20100108 at 3.) The Examiner asserted that "[t]he claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention." (Id.) The Examiner also asserted that "[t]his is a New Matter rejection." (Id.)

In making the rejection, the Examiner asserted that "[c]laims 7 and 21 have been amended to include the limitation --the fat soluble active ingredient is present in a plant or animal oil or fat-- there is no support for this limitation in the specification as originally filed. The examiner cannot find support for the limitation that the "fat soluble active ingredient is present in a plant or animal oil or fat" in the specification at paragraph [0008] (as published) or in claims 6 or 7 as originally filed, as indicated by applicant in the reply dated 11/27/2009." (Id.)

To forward prosecution in the present application, claims 7 and 21 have been amended. Claim 7 has been amended to recite "[t]he formulation according to claim 1, comprising additionally a plant or animal oil or fat." Claim 21 has been amended to recite "[t]he formulation according to claim 20, comprising additionally a plant or animal oil or fat." The amended claims are supported by the specification and original claims as noted above, particularly by original claim 7. *See In re Gardner*, 177 USPQ 396, 397 (CCPA 1973); and MPEP §§ 608.01(o) and (l). Original claim 7 recites "[f]ormulations according to claim 1, wherein the fat-soluble active ingredient is a plant

or animal oil or fat, particularly sunflower oil, palm oil or corn oil," and original claim 1 recites that the stable powderous formulations comprise "a fat-soluble active ingredient...." The specification also discloses that a fat-soluble active ingredient is a component of the powderous formulations. *See, e.g.*, the Abstract. In addition, the specification discloses that the "formulations of this invention may further contain ... a triglyceride...." (Paragraph 15, lines 1-3.) As one skilled in the art knows, triglycerides are constituents of vegetable oils and animal fats. The specification states that "[t]he triglyceride is suitably a vegetable oil or fat, such as corn oil, sunflower oil, soybean oil, safflower oil, rape seed oil, arachis oil, palm oil, palm kernel oil, cotton seed oil or cocos oil." (Paragraph 17.) One skilled in the art would understand from the specification and original claims that the inventors were in possession of the invention as presently claimed at the time of filing.

In addition, we note the Examiner's assertion with respect to a rejection under 35 U.S.C. § 103 concerning certain vegetable oils that "it would have been *prima facie* obvious to a person having ordinary skill in the art at the time the claimed invention was made that the recited oils (sunflower, corn and palm) comprise vitamins, carotenoids and/or polyunsaturated fatty acids (hereafter VCP) as evidenced by the Merck Index entries for said oils." (Paper No. 20100108 at 11.) As the Examiner has acknowledged that vegetable oils may comprise one or more fat-soluble active ingredients as recited in claim 1, it stands to reason that the claimed powderous formulation may comprise a plant oil. Likewise, because animal fats may comprise one or more fat-soluble active ingredients as recited in claim 1, it stands to reason that the claimed powderous formulation may comprise an animal fat.

In view of all of the foregoing, it is submitted that the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

Indefiniteness Rejection

Claims 2 - 4 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. (Id. at 4.)

In making the rejection, the Examiner asserted that "[c]laims 2-4 are rejected as being indefinite because the claims recite --the lupin protein-- and each depend from claim 1 which recites the narrower limitation --a native lupin protein--. It is unclear what type of lupin protein is required by claims 2-4." (Id.)

To forward prosecution in the present application, claims 2-4 have been canceled without prejudice. For this reason alone, the rejection should be withdrawn.

Obviousness Rejections

A. <u>Claims 1-5, 7-9, 15 and 18-23 over Schneider in view of Jones and Fitchett</u>

Claims 1-5, 7-9, 15 and 18-23 were rejected under 35 U.S.C. § 103(a) as obvious over Schneider, U.S. Patent No. 5,356,636 ("Schneider") in view of Jones, U.S. Publication 2002/0187185 ("Jones") and Fitchett, WO 1999/11143 ("Fitchett"). (Id. at 4.)

Schneider discloses "[a] process for preparing stable dry powders which are insoluble in hot water and which contain fat-soluble vitamins and/or carotenoids, which comprises the following steps: a) preparing an aqueous dispersion containing essentially these fat-soluble active substances, film-forming colloids and reducing

sugars, b) converting this dispersion into dry vitamin and/or carotenoid products in powder form and c) thermally curing the powder at from 60° to 180° C., wherein gelatin in combination with one or more organic amino compounds which are free or bonded in the manner of a salt and which contain a basic primary amino group and, in addition, either another amino group, a hydroxyl group, an alkoxy group or a carboxyl group, and/or in combination with sufficient basic alkali metal or alkaline earth metal compound for the dispersion to have a pH of from 7.5 to 10, is used as film-forming colloid, and the dry powders obtainable via this process are described." (Abstract.)

Jones discloses "[t]he use of a protein of vegetable origin suitable in capsule or microcapsule manufacture, which protein (a) has a molecular weight of at least 40 kD; and (b) is water soluble, whereby a clear aqueous solution can be formed that can produce a clear film on drying." (Abstract.)

Fitchett has been summarized on the record. For the Examiner's convenience, we note here that Fitchett is directed to "lupin protein compositions, and particularly to lupin protein concentrates and isolates. (Abstract, line 1.) "In particular," Fitchett is directed to "oil:water emulsions stabilized by lupin protein compositions and to gels comprising lupin protein compositions." (Abstract, line 2.) Fitchett also discloses processes for preparing emulsions and gels. (See, e.g., Summary of the Invention, page 2, lines 34 to page 5, line 32.) In addition, Fitchett discloses "various functional food ingredients comprising the emulsion or gel of the invention." (Page 4, lines 19-20.)

In making the rejection, the Examiner made the following assertions regarding the cited documents:

SCHNEIDER teaches a process for preparing stable dry powders which are insoluble in hot water and which contain fat-soluble vitamins and/or carotenoids comprising preparing an aqueous emulsion of the fat-soluble active ingredient, a film forming colloid (gelatin) and a reducing sugar, converting the emulsion into a dry powder and submitting the dry powder to cross-linking of the proteins by heat treatment (abstract).

SCHNEIDER further teaches, "The fat-soluble vitamins include vitamins A, E, D and K as well as mixtures thereof. For the purpose of the present invention they can be employed in the form of vitamin solutions in oils ... Particularly interesting products contain vitamin A and its derivatives, especially vitamin A acetate, vitamin A palmitate..." (3:59-66). SCHNEIDER further teaches the sugars can be any reducing sugars or syrup containing reducing sugars including fructose, glucose, lactose, maltose, xylose, arabinose, ribose and invert sugar (4:11-17). SCHNEIDER further teaches, "In addition to the obligatory ingredients, it is advantageous to add to the dispersion other compounds customary in the preparation of active substance dry powders" (4:59-63). SCHNEIDER goes on to teach the additives starch, maltodextrin, alginates (5:8-9) and hydrophobic silica [(5:42)].

JONES teaches a gelatin substitute (title) of vegetable origin suitable [for use] in capsule or microcapsule manufacture (abstract). JONES further teaches their invention relates to new vegetable derived protein materials which have good physical properties and may be used to replace gelatin in a diverse range of applications, especially in pharmaceutical capsule manufacture ([0001]). JONES further teaches commercial uses for gelatin have been established in a wide range of industries, including applications in food, pharmaceutical, medicinal, photographic, cosmetic and technical products ([0003]). JONES further teaches gelatin is also used for the microencapsulation of oils and vitamins (especially vitamins A and E) for edible and pharmaceutical uses ([0003]). JONES further teaches microcapsules comprising oils are normally in the form of a granular powder [...] and are formed by first emulsifying the oil phase in gelatin solution then spray-drying or spray-chilling the emulsion ([0005]). JONES further teaches the ability of gelatin to stabili[z]e the emulsion is an important feature [and] the gelatin may be

> extended by the inclusion of sugars [...] to lower the cost of production ([0005]).
>
> JONES teaches:
>
> [0006] Despite the outstanding properties exhibited by gelatin, alternatives to gelatin are currently being sought, particularly in the Pharmaceutical industry. This is partly due to religious and vegetarian pressures, which have created a desire to move to non-animal based products. Unsubstantiated concerns over gelatin presenting a potential risk from BSE (bovine spongiform encephalopathy) have also fuelled interest in alternatives.
>
> JONES teaches their invention overcomes many of the disadvantages of the current gelatin alternatives for encapsulating applications by using high molecular weight, water-soluble proteins, derived from vegetable sources ([0016]). JONES further teaches the high-molecular weight soluble proteins may be produced by a combination of hydrolysis and cross-linking reactions [... by, for example...] heat treatment of dry protein ([0040] & [0041]). JONES further teaches the preferred protein starting materials are 'isolates', since they contain the highest protein content, however, protein 'concentrates' and protein meals can also be used ([0042]). JONES further teaches the examples of suitable vegetable-derived protein raw materials include lupin, inter alia ([0044], [0057] and claim 15). [Paper No. 20100108 at 5-7.]

The Examiner asserted that "[t]he difference between the rejected claims and the teachings of SCHNEIDER and JONES is that SCHNEIDER and Jones do not expressly teach a native lupin protein; or the lupin protein isolate concentrations. The deficiencies in the native lupin protein and the lupin protein isolate concentrations are cured by FITCHETT." (Id. at 7-8.)

The Examiner further asserted that "FITCHETT teaches lupin protein compositions (abstract), which are vegetable protein concentrates (50-90% protein), and protein isolates (90+% protein) are widely used in the food industry (pg. 1, lines 9-15). FITCHETT further teaches 'Lupins have long been recognized as a viable

alternative to soya as a source of vegetable protein for human consumption' (pg. 2, line 7). FITCHETT further teaches 'It has long been known that the protein content of lupin seeds is equal to that of whole soya beans, and it has been exploited for years as a sources of (non-functional) protein in animal feeds' (pg. 2, lines 12-14). FITCHETT further teaches, the lupin protein is preferably present in substantially native form which is associated with higher functionality (pg. 4, lines 10-12)." (Id. at 8.)

The Examiner concluded that "[i]t would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of JONES and FITCHETT with SCHNEIDER because SCHNEIDER teaches a stable dry powder comprising a fat-soluble active substance encapsulated in a cross-linked gelatin protein, JONES teaches a gelatin protein substitute lupin and FITCHETT teaches lupin protein compositions. A person having ordinary skill in the art would have been motivated to use the protein gelatin substitute, lupin protein taught by JONES and FITCHETT, in the invention of SCHNEIDER because, as taught by JONES, alternatives to gelatin are being sought because of the consumer desire to have vegetable-based alternatives to animal-based gelatin." (Id. at 8-9.) The Examiner further asserted that "[f]rom the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary." (Id. at 9.)

As part of the Examiner's "Response to Argument" section, the Examiner asserted as follows:

> Applicant's arguments against the reference FITCHETT have been considered, however, in view of the new grounds of rejection (wherein FITCHETT is no longer the primary reference), most of applicant's arguments are moot. The arguments that remain relevant are addressed below.
>
> Applicant's argument that there would be no suggestion or motivation to choose native lupin protein [which is taught by FITCHETT] is not convincing because FITCHETT teaches the preferred form of lupin protein is the native form:
>
> > As described in more detail below, the lupin protein for use according to the invention may be provided in any suitable form or physical state. Preferably, it is present in substantially native form, since this is usually associated with higher functionality. It is also preferably debittered, for the reasons described in more detail below.
>
> (p. 4, lines 9-12). [Paper No. 20100108 at 17 (emphasis in original.)]

Initially, we note that the Examiner has erred in characterizing Jones as "[teaching] a gelatin protein substitute ***lupin***...." (Id. at 8) (emphasis added.) As indicated in subsequently presented arguments, Jones teaches away from the use of lupin protein. In view of the mischaracterization of Jones, the rejection should be withdrawn for this reason alone.

It is well settled the Examiner bears the burden to set forth a *prima facie* case of unpatentability. *In re Glaug*, 62 USPQ2d 1151, 1152 (Fed. Cir. 2002); *In re Oetiker*, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); and *In re Piasecki*, 223 USPQ 785, 788 (Fed. Cir. 1984). If the PTO fails to meet its burden, then the applicant is entitled to a patent. *In re Glaug*, 62 USPQ2d at 1152.

When patentability turns on the question of obviousness, as here, the search for and analysis of the prior art by the PTO should include evidence relevant to the finding of whether there is a teaching, motivation, or suggestion to select and modify the document(s) relied on by the Examiner as evidence of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1731-32 (2007) (the obviousness "***analysis should be made explicit***" and the teaching-suggestion-motivation test is "***a helpful insight***" for determining obviousness) (emphasis added); *McGinley v. Franklin Sports*, 60 USPQ2d 1001, 1008 (Fed. Cir. 2001). Moreover, the factual inquiry whether to modify document(s) must be thorough and searching. And, as is well settled, the teaching, motivation, or suggestion test "***must be based on objective evidence <u>of record</u>***." *In re Lee*, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002) (emphasis added). *See also Examination Guidelines for Determining Obviousness*, 72 Fed. Reg. 57526, 57528 (October 10, 2007) ("The key to supporting any rejection under 35 USC § 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious.").

Respectfully, we submit that the rejection is devoid of a proper section 103 analysis in support of the proposed modifications. All that is there are conclusory statements such as the assertion that "[i]t would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of JONES and FITCHETT with SCHNEIDER because SCHNEIDER teaches a stable dry powder comprising a fat-soluble active substance encapsulated in a cross-linked gelatin protein, JONES teaches a gelatin protein substitute lupin and FITCHETT teaches lupin protein compositions. A person having ordinary skill in the art would have

been motivated to use the protein gelatin substitute, lupin protein taught by JONES and FITCHETT, in the invention of SCHNEIDER because, as taught by JONES, alternatives to gelatin are being sought because of the consumer desire to have vegetable-based alternatives to animal-based gelatin." (Paper No. 20100108 at 8-9.)

Here, what the rejection should have done, but did not, was to explain on the record ***why*** one skilled in this art would modify the disclosures of Schneider, Jones, and Fitchett in the manner proposed by the Examiner to arrive at the claimed stable powderous formulation. As is well settled, an Examiner cannot establish obviousness by locating documents which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force which would impel one skilled in the art to do what the patent applicant has done. *Takeda Chem. Indus., Ltd v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. June 28, 2007) (citing *KSR*) (indicating that "it remains necessary to identify ***some reason*** that would have led a chemist to modify a known compound in a particular manner to establish *prima facie* obviousness of a new claimed compound") (emphasis added); *Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993). But this is precisely what the Examiner has done here. Thus, the rejection is legally deficient and should be withdrawn for this reason alone.

To forward prosecution in the present application, claim 1 has been amended to recite "[a] stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt.-%, wherein the protein in the matrix is cross-linked and the fat-soluble active ingredient is selected from the

group consisting of vitamin A, vitamin D, vitamin E, vitamin K, a carotenoid, a polyunsaturated fatty acid, esters of any of the foregoing, and mixtures of any of the foregoing."

To forward prosecution in the present application, claim 18 has been amended to recite "[a] stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt.-%, wherein the protein in the matrix is cross-linked with a reducing sugar."

We note that claim 7 has also been amended as noted above.

Schneider does not disclose, suggest, or provide motivation for the claimed stable powderous formulation. Schneider discloses a method to produce dry powders which are insoluble in hot water and which comprise fat-soluble vitamins and/or carotinoids, film-forming colloids and reducing sugars. (Abstract.) The use of gelatin is disclosed by Schneider. (Abstract, line 12.) An object of Schneider is to "have a lower content of costly gelatin but at least equivalent stability to hydrothermal and mechanical stress...." (Col. 2, lines 23-27.) Schneider discloses that "gelatin in amounts of from 20 to 35% of the weight of the powder dry matter, in combination with one or more physiologically tolerated organic amino compounds ... and/or in combination with sufficient basic alkali metal or alkaline earth metal compound for the dispersion to have a pH of from 7.5 to 10, is used as a film-forming colloid." (Col. 2, lines 45-55.) ***Yet no plant protein is disclosed or suggested by Schneider either in addition to or as a replacement for gelatin***. And, Schneider provides no motivation to

use a plant protein, let alone a native lupin protein isolate, to replace gelatin either in whole or in part.

Jones does not disclose, suggest, or provide motivation for the claimed stable powderous formulation. Jones discloses the use of protein of vegetable origin as a substitute for gelatin for use in capsule and microcapsule manufacture. (Title; paragraphs 6 and 17.) Jones acknowledges that there are "vegetable proteins [that] are commercially available in reasonably high purity, in the form of isolates.... Such isolates available include those derived from soya, wheat, pea and lupin." (Paragraph 12, lines 1-5.) Jones also discloses, however, that "***such vegetable protein isolates [including lupin isolates] are unsuitable*** for use in capsule production, not least because they are not fully soluble in water." (Paragraph 13, lines 1-3) (emphasis added.) Jones also discloses that even when "[t]he solubility of isolates [is] increased..., such commercially-available products ... do not form clear aqueous solutions." (Paragraph 13, lines 7-11.) And, "[b]y more extensive hydrolysis of vegetable protein, [such proteins] are unsuitable for capsule production since such films are weak and brittle, and lack mechanical strength." (Paragraph 14, lines 1-8.) In view of the foregoing, Jones leads one skilled in the art away from the use of a vegetable protein isolate including a lupin isolate in capsule or microcapsule manufacture. And, the Examiner has failed to acknowledge, let alone address this clear teach away.

In addition, Jones does not disclose, suggest, or provide motivation for a stable powderous formulation comprising a fat-soluble ingredient in a matrix formed from a plant protein such as a native lupin protein isolate. Jones discloses making a suspension using a vegetable protein suitable for capsule or microcapsule manufacture

to form a clear aqueous solution and to produce a clear film on drying. (Paragraphs 17-20.) Jones discloses the use of a vegetable protein having a molecular weight of at least 40 kD (paragraphs 17-18), and the optional use of cross-linking to create larger protein chains. (Paragraphs 40-41.) Jones does not, however, disclose or suggest preparing a fat-soluble active ingredient in a matrix formed from a native lupin protein isolate. Rather, Jones discloses preparing a clear aqueous solution that forms a film to produce a discrete container, i.e., ***clear capsule walls***. (Paragraph 47, lines 1-6.) The film according to Jones is used for coating purposes and must have different properties from the claimed formulation. In no way does Jones's encapsulation of a substance within the container formed by capsule walls provide any suggestion or motivation to achieve ***cross-linking which results in a matrix in which the fat-soluble active ingredient is finely distributed***.

Nor does Jones suggest or provide motivation for producing a ***powderous*** formulation. ***Jones lacks any enabling disclosure*** of preparing a powderous formulation. Jones does not suggest or provide motivation for the claimed stable powderous formulation in which a fat-soluble active ingredient is in a matrix formed from a native lupin protein isolate. In view of the foregoing, the rejection has been rendered moot.

Moreover, as indicated above, Jones leads one skilled in the art away from the use of a native lupin protein isolate. As is well settled, doing what an asserted document teaches against is the antithesis of obvious. *See, e.g., In re Buehler*, 515 F.2d 1134 (CCPA 1975) and *In re Rosenberger*, 386 F. 2d 1015 (CCPA 1967). Thus, for this reason also, the rejection should be with withdrawn.

Arguments presented on the record regarding Fitchett are incorporated here in their entirety.

There is no teaching, suggestion, or motivation provided by Fitchett to achieve the presently claimed powderous formulation. Fitchett does not disclose, suggest or provide motivation for a ***powderous*** formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein isolate. Also, Fitchett provides no suggestion or motivation for the claimed powderous formulation wherein the protein in the matrix is ***cross-linked***. Rather, Fitchett is directed to "oil:water emulsions stabilized by lupin protein compositions and to gels comprising lupin protein compositions." (Abstract, line 2.) No suggestion or motivation for cross-linking of protein in a matrix in a powderous formulation is provided by Fitchett. Also, ***Fitchett lacks any enabling disclosure*** of preparing a powderous formulation, let alone a powderous formulation as claimed in which the native lupin protein isolate of the matrix is cross-linked. Furthermore, there is no suggestion or motivation in Fitchett for the claimed powderous formulation to comprise a ***fat-soluble active ingredient*** in the matrix, as claimed.

As we have noted on the record, Fitchett discloses the use of lupin protein in a variety of physical states, "i.e., whether native, more or less denatured, derivatized, sub-fractionated, etc." (Page 3, lines 33-35.) And, Fitchett discloses processes in which "the structural integrity and/or solubility of the lupin protein may be decreased (at least to some extent) by the treatment (without necessarily compromising, and in some circumstances actually improving, functionality). Thus, the treatment may effect a degree of denaturation of the native lupin proteins..." (Page 5, lines 28-31.) In

particular, Fitchett discloses that "[i]t may ... be desirable to derivatize or physically modify the lupin protein, for example, by (at least partially) denaturing the proteins (e.g., by heating) or by (e.g., partial) enzymic digestion (e.g., protease treatment to yield peptides)." (Page 6, lines 8-10.) Importantly, we point out that denaturing by heating or enzymatic digestion are ***not*** processes for protein cross-linking. Fitchett further discloses that these and other disclosed approaches "can be used to modify the fat/water binding characteristics of the lupin protein and so optimize the emulsion stabilizing properties..." (Page 6, lines 11-13.)

Although the Examiner has pointed out that Fitchett states that "[p]referably, [lupin protein] is present in substantially native form, since this is usually associated with higher functionality" (Paper No. 20100108 at 17, citing Fitchett page 4, lines 9-11), in no way does Fitchett suggest that "higher functionality" has any relation to preparing a powderous formulation comprising a matrix of cross-linked lupin protein isolate in which a fat-soluble active ingredient is dispersed. And, in view of the above, Fitchett indicates that the variety of physical states of lupin protein may be equivalent in terms of emulsion stabilizing properties. Moreover, Fitchett discloses that denaturation may "in some circumstances actually [improve] functionality." (Page 5, line 30.) Fitchett thus provides no suggestion or motivation to choose native lupin protein isolates out of the variety of disclosed physical states of lupin protein, for use in the claimed powderous formulation.

Furthermore, Fitchett's disclosure of treating lupin protein with heat or enzymic digestion, e.g., protease treatment, involves breaking down, i.e., denaturation of the protein. As noted, Fitchett discloses treatments that ***denature or break down***

lupin protein, ***whereas cross-linking*** which forms a matrix in accordance with the claimed invention ***reinforces*** the protein by forming additional linkages and connections. As disclosed in the specification with regard to the claimed invention, "cross-linked formulations have been found to exhibit increased stability." (Para 10, lines 5-7) (emphasis added.) Fitchett's disclosure of denaturing lupin protein for emulsion stabilization is antithetical to cross-linking native lupin protein to form a matrix, and achieve the claimed stable powderous formulation comprising a fat soluble active ingredient in the matrix.

As is well settled, to do what the prior art teaches against is the very antithesis of obviousness. See, *e.g., In re Rosenberger*, 156 USPQ 24, 26 (CCPA 1968) and *In re Buehler*, 185 USPQ 781, 787 (CCPA 1975). At a minimum, the fact that Fitchett suggests that procedures involving lupin denaturation are equivalent to other procedures using lupin protein in an emulsion indicates that there is no suggestion or motivation provided by Fitchett to use ***native lupin protein isolates*** to achieve the claimed stable powderous formulation, let alone in which the claimed stable powderous formulation comprises a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein ***the protein in the matrix is cross-linked***. Furthermore, Fitchett provides no teaching, suggestion, or motivation regarding native lupin protein isolate in the matrix cross-linked with a ***reducing sugar***.

The Examiner cannot simply ignore the numerous and varied equivalents disclosed by Fitchett, and yet provide no reason why one skilled in the art would have chosen the aspects of Fitchett that the Examiner contends are similar to the claimed invention, and then make the asserted modifications, also without a sufficient indication

as to why, to allegedly result in the claimed powderous composition, whether in view of Fitchett alone or in combination with any or all of the other documents cited. Moreover, there are disclosures of equivalent embodiments in Fitchett that could lead one skilled in the art in a direction away from the claimed invention. The Examiner has not and can not reconcile these deficiencies in the rejection regarding Fitchett.

Furthermore, Fitchett provides no disclosure from which one skilled in the art would glean any information regarding how one could prepare a matrix using native lupin protein, and ultimately the claimed stable powderous formulation. In connection with the lack of enabling disclosure in Fitchett, it is pointed out, as noted above, that the heat treatments of Fitchett are disclosed as being ***denaturing*** to the lupin protein, which procedure is counter to cross-linking to form a matrix as in the claimed invention. Furthermore, nowhere in Fitchett is it disclosed or suggested to add a reducing sugar and apply heat or treat with a cross-linking enzyme such as a transglutaminase to effect cross-linking, as in accordance with the claimed invention. (*See, e.g.*, the specification at paragraphs 9-11.) In addition, Fitchett does not disclose or suggest a powderous form of an emulsion comprising native lupin protein isolate.

There is no suggestion in the cited documents, Schneider, Jones, and Fitchett, whether alone or in combination, that cross-linking a native lupin protein isolate would be useful to form a matrix in which a fat-soluble ingredient could be dispersed in order to prepare stable powderous formulations as presently claimed. Schneider discloses a formulation that reduces the amount of gelatin used; yet no plant protein is disclosed or suggested. Jones differs markedly from the claimed formulation in its focus on capsules rather than a lupin protein isolate in a matrix that is cross-linked in which a

fat-soluble active ingredient is dispersed. And, Jones does not disclose a powderous formulation. Jones even leads one skilled in the art away from the use of lupin isolates. Fitchett does not disclose a powderous formulation in which a native lupin protein isolate is cross-linked to form a matrix in which a fat-soluble acitive ingredient is dispersed. Moreover, Fitchett discloses denaturation of lupin protein, the antithesis of cross-linking.

Furthermore, assuming the combination of Schneider, Jones, and Fitchett, is proper, which we submit it is not, would not lead to the invention as claimed in the present application. Even if a skilled person would have considered the three disclosures together (which is contested), the Examiner could not make the present rejection based upon the disparate disclosures of the cited documents without impermissible hindsight. Without the disclosure of the present application, a skilled person had no reason to modify Schneider, Jones, and Fitchett or to expect from the disclosures of these documents that the claimed stable powderous formulations could advantageously be achieved.

Workers in the field may have considered possible alternative ways to formulate stable powderous formulations comprising a fat-soluble active ingredient, yet achieving formulations as claimed would not have been predictable to one of skill in the art. Here, known options were not "finite, identified, and predictable," as in the facts presented in *KSR Int. Co. v. Teleflex, Inc.*, 127 S. Ct. 1727 (2007). Moreover, in *Abbott Labs. v. Sandoz, Inc.*, 89 USPQ 1161, 1171 (Fed. Cir. 2008), the Court of Appeals for the Federal Circuit indicated that the Supreme Court in *KSR* "did not create a presumption that all experimentation in fields where there is already a background of

useful knowledge is 'obvious to try,' without considering the nature of the science or technology."

The Court of Appeals for the Federal Circuit has reaffirmed that "hindsight claims of obviousness" are improper. In distinguishing between fact patterns where a combination of known elements may or may not be proper, the Federal Circuit clearly articulated that simply varying all possible parameters until the claimed invention is arrived at in the absence of either an indication of which parameters to vary or an indication of which of many possible choices is likely to be successful is impermissible hindsight reconstruction. Indeed, the Federal Circuit concluded:

> Similarly, patents are not barred just because it was obvious "to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 90 USPQ2d 1947, 1951 (Fed. Cir. 2009), *citing In re O'Farrell*, 853 F.2d at 903.
>
> As in the *Abbott* case, one skilled in the art would not have anticipated success in achieving the presently claimed stable powderous formulations comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein isolate, as "knowledge of the goal does not render its achievement obvious." *Abbott Labs. v. Sandoz, Inc.*, 89 USPQ at 1172 (affirming the district court's determination that Abbott is likely to prevail in its claim that the patent is valid, and upholding the grant of a preliminary injunction).

Clearly, the Examiner's rejection is based on impermissible hindsight reconstruction and is improper. It is submitted that the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

B. Claim 14 over Schneider in view of Jones, Fitchett, and Tashiro, and as evidenced by the Merck Index

Claim 14 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Schneider in view of Jones and Fitchett, as applied to claims 1-5, 7-9, 15 and 18-23 above, and further in view of Tashiro, U.S. Patent No. 4,855,157 ("Tashiro"), and as evidenced by the Merck Index (entries for "Sunflower Seed Oil," "corn oil" and "Oil Palm"). (Paper No. 20100108 at 9.)

Schneider, Jones, and Fitchett are summarized above.

Tashiro discloses "[a] process for producing fat powder which comprises contacting a fat or oil in the form of liquid drops in an atomized state with air flow at a low temperature, the fat or oil containing a non-oil soluble natural solid material uniformly dispersed therein." (Abstract.) Tashiro also discloses that "[t]he non-oil soluble natural solid used material [sic] in the present invention include [sic] wheat flour, soybean powder, corn flour, rice flour, sugars, starch, dextrin, gums, protein, skim milk powder, whole milk powder, whey powder, casein, sodium caseinate, cacao mass, cacao powder, pepper, seasonings and the like." (Col. 2, lines 44-50.)

The portions of the Merck Index cited by the Examiner disclose the chemical compositions of sunflower seed oil, palm oil, and corn oil.

The Examiner made the following assertions regarding the cited documents:

> SCHNEIDER teaches a [sic] stable dry powders which contain fat-soluble vitamins and/or carotenoids, which are prepared as using the film-forming colloid gelatin, as discussed above.
>
> JONES teaches a gelatin substitute (title) of vegetable origin suitable [for use] in capsule or microcapsule

> manufacture; the microencapsulation of oils and vitamins (especially vitamins A and E) for edible and pharmaceutical use; and the example of a suitable vegetable-derived protein raw material lupin, as discussed above.
>
> FITCHETT teaches lupin protein compositions (abstract), which are vegetable protein concentrates (50-90% protein), and protein isolates (90+% protein) [that] are widely used in the food industry; and the lupin protein is preferably present in substantially native form which is associated with higher functionality, as discussed above.
>
> SCHNEIDER and JONES do not teach the oil species sunflower oil, palm oil or corn oil. This deficiency in the oil species is cured by the teachings of TASHIRO as evidenced by the Merck Index.
>
> TASHIRO teaches two known [processes] for producing a fat containing powder [including], first spray-drying a fat or oil which has been emulsified into an oil-in-water type emulsion, and second atomizing a molten fat or oil in an atmosphere at a temperature that is lower than the melting point of the fat or oil (1 :9-19). TASHIRO further teaches sunflower oil, corn oil, and palm oil, inter alia (2:27).
>
> The Merck Index teaches sunflower seed oil comprises 66.2% of the polyunsaturated fatty acid linoleic acid and 75mg/100g of Vitamin E. The Merck Index teaches oil palm comprises 10% linoleic acid, carotenoids, and tocopherols (vitamin E). The Merck Index teaches corn oil comprises 34-62% linoleic acid and y-tocopherol (vitamin E). [Paper No. 20100108 at 10-11.]

The Examiner asserted that "[t]herefore, it would have been *prima facie* obvious to a person having ordinary skill in the art at the time the claimed invention was made that the recited oils (sunflower, corn and palm) comprise vitamins, carotenoids and/or polyunsaturated fatty acids (hereafter VCP) as evidenced by the Merck Index entries for said oils." (Id. at 11.)

The Examiner concluded that "[i]t would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of TASHIRO with the teachings of SCHNEIDER because SCHNEIDER

teaches products comprising vitamins in oils and TASHIRO teaches the VCP containing oil sunflower oil, corn oil, and palm oil. A person having ordinary skill in the art would have been motivated to combine the VCP containing oil of TASHIRO with the composition because the oils taught by TASHIRO would have been widely available and would provide for a more nutritious and therefore desirable product." (Id.)

The Examiner further asserted that "[f]rom the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary." (Id.)

To forward prosecution in the present application, claims 1 and 7 upon which claim 14 depends have each been amended as noted above.

The arguments provided in section A above in response to the rejection of claims 1-5, 7-9, 15, and 18-23 over Schneider in view of Jones and Fitchett are incorporated herein. For those reasons alone, the rejection has been rendered moot.

In addition, it is submitted that Tashiro provides no disclosure, suggestion, or motivation to use lupin protein, let alone native lupin protein isolate, in a process for producing fat powder. Furthermore, Tashiro provides no motivation or expectation of success in preparing a stable powderous formulation comprising a cross-linked native lupin protein isolate as a matrix in which a fat-soluble active ingredient is dispersed.

And the chemical compositions of sunflower seed oil, palm oil, and corn oil noted by the Examiner from the Merck Index also provide no disclosure, suggestion, or motivation to achieve the subject matter of claim 14.

For all of the foregoing reasons, it is submitted that the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

C. Claims 11-13, 16 and 17 over Schneider in view of Jones, Fitchett and Gerrard, and as Evidenced by Siepaio

Claims 11-13, 16 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Schneider in view of Jones, Fitchett and Gerrard, *Trends in Food Science and Technology*, 13, 2002, pp. 391-399 ("Gerrard"); and as evidenced by Siepaio, *Journal of Agricultural and Food Chemistry*, 1995, Vol. 43, pp. 1151-1156 ("Siepaio"). (Paper No. 20100108 at 11-12.)

Schneider, Jones, and Fitchett are summarized in section A above.

Gerrard has been summarized on the record. For the Examiner's convenience, we note that Gerrard discloses "[p]rotein-protein crosslinking in food: methods, consequences, [and] applications." (Title.) Various types of crosslinking are disclosed. (Pages 391-394, including Figs. 1 and 2.)

Siepaio discloses "diamine oxidase and transglutaminase activities in white lupine seedlings with respect to cross-linking of proteins." (Title.) Siepaio discloses that "[e]nzymes extracted from 10-d-old *Lupinus albus* seedlings were able to (1) polymerize casein and (2) incorporate [^{14}C]putrescine into dimethylcasein (modified

casein). .... [^{14}C]Putrescine incorporation was not only due to transglutaminase activity but also due to diamine oxidase." (Abstract, lines 1-4.)

With regard to the cited documents, the Examiner made the following assertions:

> SCHNEIDER teaches a process for preparing stable dry powders comprising the steps of (a) preparing an aqueous dispersion containing fat-soluble [vitamins or carotenoids], film-forming colloids, and reducing sugars; (b) converting this dispersion into a dry vitamin and/or carotenoids products in powder form; and (c) thermally curing the powder at from 60°C to 180°C (abstract). SCHNEIDER further teaches the thermal treatment of the initially obtained powder results in the gelatin content being denatured owing to reaction of its free amino groups with the reducing sugars (Maillard reaction) (3:34-37). SCHNEIDER further teaches the process according to their invention has the advantage that the customary crosslinking temperatures are reduced in the presence of amino compounds and/or the basic compounds (i.e. crosslinking is possible at 60°C or above) (3:48-53).
>
> JONES teaches a gelatin substitute (title) of vegetable origin suitable [for use] in capsule or microcapsule manufacture; the microencapsulation of oils and vitamins (especially vitamins A and E) for edible and pharmaceutical use; and the example of a suitable vegetable-derived protein raw material lupin, as discussed above. JONES teaches their invention overcomes many of the disadvantages of the current gelatin alternatives for encapsulating applications by using high molecular weight, water-soluble proteins, derived from vegetable sources ([0016]). JONES further teaches the high-molecular weight soluble proteins may be produced by a combination of hydrolysis and cross-linking reactions [and the cross-linking reactions] may include the controlled use of the enzyme transglutaminase, which is capable of forming cross-links between glutamine and lysine residues in the protein chains ([0040]).
>
> FITCHETT teaches lupin protein compositions (abstract), which are vegetable protein concentrates (50-90% protein), and protein isolates (90+% protein) are widely used in the food industry; and the lupin protein is preferably

present in substantially native form which is associated with higher functionality, as discussed above.

GERRARD teaches methods for protein-protein crosslinking including the use of transglutaminase catalysis (p. 394, lines 27-56, col. 2 lines 1-2). GERRARD further provides the motivation to use enzymes for protein-protein crosslinking (p. 395, col. 1):

Enzymatic Methods

The use of enzymes to modify the functional properties of foods is an area which has attracted considerable interest, since consumers perceive enzymes to be more 'natural' than chemicals. Enzymes are also favoured as they require milder conditions, have high specificity, are only required in catalystic quantities, and are less likely to produce toxic products (Singh, 1991). Thus enzymes are becoming commonplace in many industries for improving functional properties of food proteins (Chobert et al., 1996; Poutanen, 1997).

SIEPAIO teaches:

(Signorini et al. 1991). In order to diversify the supply of TGase, we have looked for a TGase in white lupine seedlings.

(p. 1151, introduction last line of first paragraph; TGase = transglutaminase). And SIEPAIO confirmed the presence of transglutaminase in lupine seeds:

...This experiment confirmed that the TGase contained in the 41400g pellet either was an integral membrane protein or was bound to the integral membrane protein...

(p. 1152, col. 2, last line; and p. 1153, col. 1, lines 1-3).
[Paper No. 20100108 at 13-15.]

The Examiner concluded that "[i]t would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of JONES and FITCHETT with SCHNEIDER because SCHNEIDER teaches a process for preparing stable dry powder comprising a fat-soluble active substance encapsulated in a crosslinked gelatin protein, JONES teaches a gelatin

protein substitute lupin and FITCHETT teaches lupin protein compositions. A person having ordinary skill in the art would have been motivated to use the protein gelatin substitute, lupin protein taught by JONES and FITCHETT, in the process of SCHNEIDER because, as taught by JONES, alternatives to gelatin are being sought because of the consumer desire to have vegetable-based alternatives to animal-based gelatin." (Id. at 15.)

The Examiner further concluded that "[i]t would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the teachings of GERRAND [sic] with the teachings of SCHNEIDER because SCHNEIDER teaches a process for making a vitamin food product containing crosslinked proteins and GERRARD teaches methods for protein-protein crosslinking useful in food products. A person having ordinary skill in the art would have been motivated to combine GERRARD with SCHNEIDER because the various different crosslinking methods, as taught by GERRARD, would have provided different routes for achieving the best possible crosslinked protein food product. And consulting the protein-protein crosslinking methods taught by GERRARD would have saved the time and money required to newly discover what is already known. A person having ordinary skill in the art would have been motivated to use a the [sic] cross-linking enzyme transglutaminase, as taught by JONES, in the invention of SCHNEIDER because, as taught by GERRARD, the consumer would have favored products using enzymes as more natural. A person having ordinary skill in the art would have had a reasonable expectation of success in using transglutaminase to crosslink lupin protein because, as

evidenced by SIEPAIO, native lupin seeds contain the enzyme transglutaminase as an active metabolic enzyme." (Id. at 15-16.)

Further, the Examiner asserted that "from the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary." (Id. at 16.)

As part of the Examiner's "Response to Arguments" section, the Examiner asserted that "Applicant's argument that Gerrard provides no disclosure that the cross-linking can be applied to lupin protein, is not convincing because the reactions taught by Gerrard can be applied to "food protein, either native or denatured" (see p. 392, Figure 1) and the described reactions would clearly apply to lupin food protein. And as evidenced by SIEPAIO, native lupin seeds contain the enzyme transglutaminase as an active metabolic enzyme." (Id. at 17.)

Initially, we note that the Examiner has erred in characterizing Jones as disclosing "the example of a suitable vegetable-derived protein raw material ***lupin***, as discussed above." (Id. at 13) (emphasis added.) As indicated in arguments presented in section A above which are incorporated here, Jones teaches away from the use of lupin protein. In view of the mischaracterization of Jones, the rejection should be withdrawn for this reason alone.

To forward prosecution in the present application, claims 11-13 have been amended. Amended claim 11 recites "[a] process for the preparation of a formulation

comprising preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt.-%, wherein a reducing sugar is added and the composition is submitted to cross-linking by heating." Amended claim 12 recites "[a] process for the preparation of a formulation comprising preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt.-%, wherein the composition is submitted to cross-linking by treatment with a cross-linking enzyme." Amended claim 13 recites "[a] process for the preparation of a powderous formulation comprising preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein composition which is a native lupin protein isolate having a protein content of more than 90 wt.-%, adding a reducing sugar, and converting the emulsion into a dry powder."

Arguments presented in section A above in response to the rejection of claims 1-5, 7-9, 15, and 18-23 over Schneider in view of Jones and Fitchett are incorporated herein. The arguments pertaining to those claims relate to the present claims to the extent that those claims may recite a product (stable powderous formulations) of the processes claimed in presently rejected claims 11-13, 16 and 17 (processes for the preparation of a formulation...)

Beyond looking at the cited documents to determine if any of them suggests doing what the present inventors have done, one must also consider if the art provides the required expectation of succeeding in that endeavor. See *In re Dow Chem. Co. v. American Cyanamid Co.*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988).

"Obviousness does not require absolute predictability, but a reasonable expectation of success is necessary." *In re Clinton*, 188 USPQ 365, 367 (CCPA 1976). Furthermore, the *U.S. Patent and Trademark Office Examination Guidelines* at page 57527 provide the following guidance to Examiners: "In short, the focus when making a determination of obviousness should be on what a person of ordinary skill in the pertinent art would have known at the time of the invention, and on what such a person would have reasonably expected to have been able to do in view of that knowledge." However, no such motivation or expectation of success can be found in the cited documents.

Gerrard's disclosure is an overview of various forms of crosslinks found in food. Gerrard provides no disclosure that the crosslinking can be applied to lupin protein, let alone native lupin protein isolate. Furthermore, Gerrard does not disclose or suggest preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein isolate, as claimed.

One skilled in the art could not have predicted success in the claimed processes using native lupin protein isolate. Gerrard discloses that "[n]ot all amino acids participate in protein crosslinking" (page 392, left col., lines 1-2), and "our understanding of crosslinking of food proteins by the Maillard reaction, and how this crosslinking relates to the functional properties of foods, remains in its infancy." (Page 394, left col., lines 11-14.)

Furthermore, Gerrard's general disclosure of the use of transglutaminase in the context of a Maillard reaction does not cure the above deficiencies.

With regard to claims 13 and 17 in particular, Gerrard fails to provide motivation for, nor an indication as to how to make, the claimed ***powderous*** formulation

comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked.

Nor does Siepaio's indication that transglutaminase is present in lupine seeds provide any suggestion or motivation to undertake the claimed processes. Siepaio discloses crosslinking of casein with enzymes obtained from lupin seedlings; there is no disclosure or suggestion of cross-linking native lupin protein isolates, whether by use of transglutaminase or otherwise. There is no indication as to whether any transglutaminase is present in a native lupine protein isolate and even if there were, whether the amount would be sufficient to effect cross-linking. In fact, Siepaio characterizes "the available amount of enzyme ... for plant TGases" as "low." (Page 1151, left col., lines 28-29.) This does not provide any motivation or expectation of success in attempting cross-linking of native lupin protein isolate and preparing an aqueous emulsion of a fat-soluble active ingredient and a native lupin protein isolate.

Even if all cited documents were properly combined (which is contested), it is submitted that the examiner could only have made the present rejection through impermissible hindsight.

In view of all of the foregoing, it is respectfully submitted that the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

Obviousness-Type Double Patenting

Claims 1, 7-9, 11 and 13 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 6,

8, 12-14, 16 and 17 of copending Application No. 10/564,635 ("the '635 Application") in view of Perrier, U.S. Patent No. 5,912,016 ("Perrier").

Perrier has been summarized on the record. For the Examiner's conceniece, we note that Perrier discloses particles, which are "microparticles or nanoparticles, of crosslinked plant proteins, ... the process for their preparation and ... cosmetic, pharmaceutical or food compositions in which they are present." (Column 1, lines 5-9) (emphasis added.) Perrier also discloses that "[t]hese particles comprise, at least on the surface, a wall formed of plant proteins crosslinked ... by means of interfacial crosslinking between the plant proteins and an acylating polyfunctional crosslinking agent comprising at least two actylating groups, covalent bonds being formed between the acylatable groups of the proteins and the acyl groups of the acylating polyfunctional crosslinking agent." (Abstract, lines 1-8.) Perrier further discloses that the produced particles are "especially spheres or capsules such as nanospheres or nanocapsules and microspheres or microcapsules, which ... encapsulate substances, particularly active principles...". (Col. 8, lines 35-39) (emphasis added.)

In making the rejection, the Examiner asserted[2]:

> Copending '635 claim 14 recites, formulations wherein the reducing sugar is glucose, fructose, saccharose, or xylose. Instant claim 8 is coextensive in scope with copending '635 claim 14. ....
>
> Copending '635 claim 1 recites, stable powderous formulations comprising a fat-soluble active

[2] It is noted that in some cases, the Examiner has recited an "abbreviated" version of pending claims of the '635 Application; for the full text of the claims of the '635 Application, the public record in PAIR for the '635 Application may be viewed.

> ingredient in a matrix of milk protein compositions, wherein the protein is thermally cross-linked with a reducing-sugar. Copending '635 claim 6 recites the formulation additionally comprises a plant protein and copending '635 claim 8 recites formulations which further comprise plant protein which is obtained from potato protein, soy protein, wheat protein, pea protein, rice protein or lupin protein. Copending '635 claim 12 recites, formulations wherein the fat-soluble active ingredient is vitamin A, D, E or K, or a carotenoid, or a polyunsaturated fatty acid; copending '635 claim 13 recites formulations wherein the fat-soluble active ingredient is mixed with a plant or animal fat. Copending '197 [sic] claim 17 recites, a process for the preparation of formulations comprising preparing an aqueous emulsion of the fat-soluble active ingredient and the milk protein composition, adding the reducing sugar, converting the emulsion into a dry powder, and submitting the dry powder to cross-linking the protein with heat treatment. [Paper No. 20100108 at 18-19.]

The Examiner asserted that "[t]he difference between Copending '635 and the instant claimed invention is that copending '635 does not explicitly teach the use of lupin protein for the primary crosslinking protein. The deficiency of using a lupin protein is cured by the teachings of PERRIER, which teaches particles of cross-linked lupin plant proteins wherein the particles encapsulate active substances, including lipophilic active principles, as discussed above. " (Id. at 19.)

The Examiner concluded that "[i]t would have been prima facie obvious to combine copending '635 with the teachings of Perrier et al. and produce the instant claimed invention because both applications teach cross-linked protein food additives with a fat-soluble active ingredient in the protein matrix. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, i.e. a cross-linked protein food additive. [citation omitted.] Furthermore, the

lupin protein of PERRIER would provide an added nutritive value to copending '635 and produce a more desirable product. It would be obvious to substitute the milk protein of '635 with the lupin protein of the instant application because it would provide access to a new market of consumers for which the milk protein would be unacceptable (e.g. vegans). (Id. at 19-20.)

In the Examiner's "Response to Arguments" section, the Examiner asserted, *inter alia*, that "Applicant's argument that Perrier simply does not disclose or suggest a formulation of a fat-soluble active ingredient in powder form, is not convincing because the copending claims of '635 recite --stable powderous formulations--, coextensive with the preamble of the instantly rejected claims. And the only limitation of the instantly claimed invention that copending 10/564,635 cannot provide is the lupin protein. (Id. at 20.)

The Examiner also asserted:

> Applicant's argument that:
> At bottom, there is simply no teaching, suggestion or motivation in Perrier for making a stable powderous formulation comprising a fat-soluble active ingredient in a matrix formed from a native lupin protein composition wherein <u>the protein in the matrix</u> is cross-linked, including with a <u>reducing sugar</u>.
> is not convincing because every limitation emphasized is recited in copending 10/564,635, claim 1:
> 1. (previously presented) Stable <u>powderous</u> formulations comprising a fat-soluble active ingredient in a <u>matrix</u> of a milk protein composition; wherein the <u>protein is thermally cross-linked</u> with a <u>reducing sugar</u> or a reducing sugar derivative selected from a desoxy sugar or an amino sugar. [Id. at 21.]

Initially, we refer to the Examiner's assertion that "[t]he deficiency of using a lupin protein is cured by the teachings of PERRIER," which the Examiner referred to as being "discussed above." (Id. at 19.) We note that in the outstanding Action (Paper No. 20100108), Perrier had not been previously addressed by the Examiner (other than its citation in the rejection).

Arguments presented on the record in response to this rejection previously made are incorporated here.

To forward prosecution in the present application, claims 1, 7, 11, and 13 have been amended as indicated above. It is noted that amended claims 1, 11, and 13 recite that the "native lupin protein composition ... is a native lupin protein isolate having a protein content of more than 90 wt.-%."

It is submitted that the Examiner has responded to arguments on the record, as noted above, by referring merely to the claims of the '635 Application. The Examiner did not (and could not) provide reasoning why Perrier would, according to the Examiner, be combined with the cited claims of the '635 Application. Nor has the Examiner provided any reason why such a combination, if proper (which is contested), would allegedly render the rejected claims obvious.

Perrier discloses encapsulating substances by means of interfacial polymerization. Perrier discloses the use of an "acylating polyfunctional crosslinking agent" in addition to plant proteins having acylatable groups, in order to encapsulate substances. (Abstract; Col. 8, lines 35-39.) Perrier's disclosure of interfacial polymerization which results in cross-linking to form a ***wall or surface***, i.e., encapsulation of a desired substance, provides no suggestion or motivation to produce

cross-linking which results in a matrix, as in the claimed stable powderous formulation. The capsule in Perrier is used for coating purposes and must have different properties from the claimed formulation. In the claimed formulation, the fat-soluble active ingredient is finely distributed in the matrix formed from a native lupin protein composition wherein the protein in the matrix is cross-linked.

Also, Perrier does not enable the preparation of either the matrix or the powderous formulation comprising a fat-soluble active ingredient in a matrix, as claimed. Perrier provides no teaching, suggestion or motivation regarding the use of a reducing sugar (or transglutaminase), to effect cross-linking to achieve the matrix for example, in claim 1, and as recited in claims 8 and 18, or the process, *e.g.*, of claims 11 and 13. One skilled in the art simply would not look to a disclosure of encapsulation using interfacial polymerization in attempting to make a cross-linked matrix, and to achieve a stable powderous formulation comprising the cross-linked matrix, as claimed. Furthermore, one would not look to Perrier to prepare a matrix of native lupin protein isolate which is cross-linked with a reducing sugar.

The use by Perrier of glucose in Example 9 is as the "water soluble active principle" which is encapsulated within "a wall formed of crosslinked lupin proteins" to provide "microcapsules ... which contain glucose." (Col. 10, line 66 to Col. 11, line 14.) In other words, glucose is the substance encapsulated within the walls of the capsule; according to Perrier's disclosure, glucose is not disclosed as an aid to crosslinking. Nor is it suggested for use in that capacity. This disclosure of the use of glucose leads one skilled in the art away from the claimed ***powderous*** formulation in which the active

ingredient is a ***fat-soluble active ingredient*** dispersed in a matrix of cross-linked native lupin protein isolate.

Perrier's disclosure of particles, such as microcapsules and nanocapsules, and methods for encapsulating substances also fails to teach, suggest or provide motivation for the claimed stable powderous formulation. One skilled in the art would not look to a disclosure of encapsulation as in Perrier in attempting to achieve a stable powderous formulation comprising a fat-soluble active ingredient in a matrix or a process for the preparation of a formulation, as claimed. And, there simply is no disclosure or suggestion in Perrier of making a ***powderous*** formulation.

Perrier also fails to disclose, suggest or provide motivation for use of native lupin protein ***isolate*** in the claimed subject matter. Examples in which lupin is used in Perrier (which is for the purpose of forming a capsule wall) disclose the use of lupin protein flour (containing 45% proteins). *See, e.g.*, Examples 1 and 9. In no way does lupin protein flour having 45% proteins suggest the use of native lupin protein isolate having a protein content of more than 90 wt.-% in the claimed inventions.

Thus, Perrier fails to fill in the gaps of the pending claims of the '635 Application. It is submitted that the rejection has been rendered moot. Reconsideration and withdrawal of the rejection are requested.

In view of all of the foregoing, entry of the amendments and withdrawal of all outstanding rejections are respectfully requested. It is submitted that the application is in condition for allowance. Issuance of a Notice of Allowance is respectfully requested. If the Examiner has any questions regarding this paper, please contact the undersigned.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on July 2, 2010.

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Respectfully submitted,

By: _____

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